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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,471	02/27/2007	Tatsuya Konishi	KPO-TSC-P3/TK-93/US	3141

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EXAMINER	
KASSA, TIGABU	

ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
11/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/560,471	KONISHI ET AL.	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-11,13,15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-11, 13, and 15-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed July 06, 2009. **Claims 8-11, 13, and 15-16 are pending.** **Claims 8-11, 13, and 15-16 are under examination in the instant office action**. Claims 1-7, 12, and 14 are cancelled. Applicant's amendment has necessitated a new ground of rejection. Accordingly, this Action is made FINAL.

Withdrawn rejections

Applicant's amendments and arguments filed on 07/06/09 are acknowledged and have been fully considered. All rejections applied in the previous office action are hereby withdrawn as a result of applicants claim amendments.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 16, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-9 are rejected under 35 U.S.C. § 102(b) as being anticipated by Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647) as evidenced by Patel et al. (US Patent No. 4855294).

Instant claim 8 recites an analgesic and anti-inflammatory patch in the form of an aqueous poultice material containing 10 to 80 % water comprising, as active ingredients, benzocaine and an ingredient having a counter-irritation effect. Instant claim 9 recites the analgesic and anti-inflammatory patch according to claim 8, containing benzocaine in an amount of 0.5 to 20 wt %.

Yamasaki et al. disclose an external skin patch having improved **painkilling effect for pains accompanied by inflammation**, such as chronic arthrorheumatism, arthrosis deformans or low back pain (see abstract). Yamasaki et al. disclose that an external skin patch is obtained by coating a drug-containing base on a substrate; the drug-containing base comprises an adhesive gel base containing a water soluble polymeric material, a crosslinking agent, water and a humectant as essential components, and a local anesthetic and a nonsteroidal antiphlogistic analgesic agent as medicinal components (see abstract). Yamasaki et al. disclose **an external skin patch comprising a formulation of benzocaine (7% w/w), based on examiner's calculation 48.3 % of water, glycerin (counter-irritant) (10%) and other ingredients** (column 6, example 2, and lines 28-54). Therefore, the above teachings clearly anticipate the limitations of instant claims 8-9.

Note: Patel et al. is incorporated in the rejection as an evidentiary reference in order to verify that glycerin is an anti-irritation agent (see abstract and claim 1).

Claim 15 is rejected under 35 U.S.C. § 102(b) as being anticipated by Juni (US Patent No. 6120792).

Juni discloses **a medicated skin patch for delivering a topical anesthetic to a region of skin which has been irritated**, the patch comprising a bibulous pad for contacting and covering the irritated region a thickened, topical anesthetic imbibed in the bibulous pad, said anesthetic comprising an active ingredient chosen from the group consisting of lidocaine, **benzocaine**, procaine, xylocaine, and combinations thereof (see claim 1). Juni discloses the medicated skin patch also contains an active ingredient of the counter-irritant composition chosen from the group consisting of **capsaicin, menthol**, and clove oil (see claim 10). Juni discloses the anesthetic imbibed in the bibulous pad in one preferred embodiment contains 10% benzocaine (column 3, lines 25-34), which addresses all the limitations of instant claims 8-10. Juni also discloses that an anesthetic such as **benzocaine** that is incorporated in a medical patch can be used to alleviate pain and skin irritations (column 3, lines 25-34 and column 1, lines 18-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically taught or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647), as applied to claims 8-9 above, and further in view of Bernstein (US Patent No. 4997853).

Applicant Claims

The claimed subject matters of instant claims 8-9 are set forth above. Instant claim 10 recites the analgesic and anti-inflammatory patch according to claim 9, wherein the ingredient having a counter-irritation effect is at least one selected from the list

recited in the instant claim. Instant claim 11 recites the analgesic and anti-inflammatory patch according to claim 10, containing the ingredient having a counter-irritation effect in an amount of 0.01 to 30 wt % when it is one of 1-menthol, d1-menthol, d1-camphor, d-camphor, methyl salicylate, glycol salicylate, mentha oil and eucalyptus oil, or in an amount of 0.001 to 5 wt % when it is one of capsaicin, one of capsicum extract and nonylic vanillylamide. Instant claim 15 recites a method of reducing irritation of the

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Yamasaki et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Yamasaki et al. do not explicitly teach the specific ingredients with counter-irritation effects listed in instant claims 10-11. Additionally, Yamasaki et al. do not explicitly teach the concentration ranges for the ingredient having a counter-irritation effect. These deficiencies are cured by the teachings of Bernstein.

Bernstein teaches a method for treating superficial pain syndromes, said method comprising the step of topically applying to a patient having superficial pain, an effective amount of a composition comprising a therapeutically acceptable carrier and capsaicin, said **capsaicin being present in a concentration, by weight, from about 0.01% to about 1.0%**, said composition also including a topical anesthetic in a therapeutically effective amount, said anesthetic being present primarily to inhibit the local topical irritant effect of said capsaicin and whereby said capsaicin provides the primary relief for the pain syndrome (see claim 1). The anesthetic can be benzocaine (see claim 3).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Yamasaki et al. by incorporating the counter-irritation agent capsaicin in the medical adhesive patch composition containing an ingredient with a counter-irritation effect such as capsaicin in a concentration of 0.001 to 5 wt %, because Bernstein teaches the similar composition containing capsaicin in concentration of from about 0.01% to about 1.0% for the same intended purpose. An ordinary skilled artisan would have been motivated to incorporate the capsaicin in concentration of from about 0.01% to about 5.0% because at higher concentrations the capsaicin can cause burning and irritation. An ordinary skilled artisan would have had a reasonable expectation of success upon combining the teachings of Yamasaki et al. and Bernstein, because both references teach the similar compositions for the same intended purpose namely relief of pain.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647) in view of Juni (US Patent No. 6120792).

Applicant Claims

Instant claim 13 recites an analgesic and anti-inflammatory patch comprising an aqueous poultice material containing 10 to 80 wt % water, 0.5 to 20 wt % of benzocaine, and at least one ingredient having a counter-irritation effect selected from the listed recited in the instant claim. Instant claim 16 recites a method of reducing pains by applying an analgesic and anti-inflammatory patch described above.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Yamasaki et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Yamasaki et al. do not explicitly teach the specific ingredients with counter-irritation effects listed in instant claims 13 and 16. This deficiency is cured by the teachings of Juni.

Juni teaches **a medicated skin patch for delivering a topical anesthetic to a region of skin which has been irritated**, the patch comprising a bibulous pad for contacting and covering the irritated region a thickened, topical anesthetic imbibed in the bibulous pad, said anesthetic comprising an active ingredient chosen from the group consisting of lidocaine, **benzocaine**, procaine, xylocaine, and combinations thereof (see claim 1). Juni teaches the medicated skin patch also contains an active ingredient of the counter-irritant composition chosen from the group consisting of **capsaicin, menthol**,

and clove oil (see claim 10). Juni teaches the anesthetic imbibed in the bibulous pad in one preferred embodiment contains 10% benzocaine (column 3, lines 25-34), which addresses all the limitations of instant claims 8-10. Juni also teaches that an anesthetic such as **benzocaine** that is incorporated in a medical patch can be used to alleviate pain and skin irritations (column 3, lines 25-34 and column 1, lines 18-20).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Yamasaki et al. by incorporating the counter-irritation agent recited in instant claims 13 and 16 in the medical adhesive patch, because Juni teaches the incorporation of counter-irritants **capsaicin, menthol**, and clove oil in a patch that may contain benzocaine to alleviate pain and skin irritation. An ordinary skilled artisan would have been motivated to substitute the counter-irritant glycerin with the other counter-irritants recited in instant claims 13 and 16 because the anti-irritations agents are functionally equivalent and can equally perform the intended purpose. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the Yamasaki et al. and Juni, because both references teach the similar compositions delivered in a patch for alleviation of pain.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647) in view of Hirashima et al. (US Patent No. 6471984).

Applicant Claims

Instant claim 13 recites an analgesic and anti-inflammatory patch comprising an aqueous poultice material containing 10 to 80 wt % water, 0.5 to 20 wt % of benzocaine, and at least one ingredient having a counter-irritation effect selected from the listed recited in the instant claim. Instant claim 16 recites a method of reducing pains by applying an analgesic and anti-inflammatory patch described above.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Yamasaki et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Yamasaki et al. do not explicitly teach the specific ingredients with counter-irritation effects listed in instant claims 13 and 16. This deficiency is cured by the teachings of Hirashima et al..

Hirashima et al. teach a patch containing a plasticizer 3-L-menthoxypropane-1,2-diol, which is excellent in overall feeling such as adhesion and fit feeling to the skin and peeling pain (see abstract). Hirashima et al. also teach a cataplasm (poultice) and a tape-

aid (plaster) each containing the plasticizer (column 1, lines 15-17). The drugs that can be used in the patch include benzocaine (column 3, line 8). **The content of the drug is preferably 0.1 to 20% by weight, more preferably 0.5 to 10% by weight, of the total amount of the base for the patch** (column 3, lines 25-27). The patch further contain various pharmacologically acceptable additives, such as a stabilizer, an antioxidant, a perfume, a filler, an ultraviolet absorber, an antiseptic, an antimicrobial agent and a percutaneous absorbefacient (column 3, lines 29-34). Hirashima et al. teach that as the base for the cataplasm, a hydrophilic base comprising a water-soluble polymer, a polyhydric alcohol and water is preferable in consideration of long-term stability, releasability and percutaneous absorbability of drug, and safety for the skin (column 3, line 41-45). In the base the content of water is preferably **10 to 90% by weight, more preferably 20 to 80% by weight**, based on the total amount of the hydrophilic base. The water is necessary in order **to solubilize the water-soluble polymer to thereby make the resulting base develop its thickening, cohesive and shape-retaining properties**. The hydrophilic base of the cataplasm may contain one or more additives, for example, ultraviolet absorbers such **glycol salicylate, methyl salicylate and phenyl salicylate** (column 4, lines 49-50), which are ingredients with counter-irritation effect.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Yamasaki et al. by incorporating the counter-irritation agent recited in instant claims 13 and 16 in the medical adhesive patch, because Hirashima et al. teaches that counter-irritants like **glycol**

salicylate, methyl salicylate and phenyl salicylate can be included in a patch that may contain drugs like benzocaine to alleviate pain and skin irritation. An ordinary skilled artisan would have been motivated to substitute the counter-irritant glycerin with the other counter-irritants recited in instant claims 13 and 16 because the anti-irritation agents are functionally equivalent and can equally perform the intended purpose. Furthermore, the ingredients with the counter irritation effect are conventionally known in the art. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the Yamasaki et al. and Hirashima et al., because both references teach similar compositions delivered in a patch for alleviation of pain.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 8-11, 13, and 15-16 are rejected. Claims 1-7, 12, and 14 are cancelled. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 11/05/09
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